

REMARKS

Claim Rejections – 35 U.S.C. § 103

Claims 1-7, 10-11, 16-23, 29-31, 33, 34, 43, 53, 58-61 and 63 have been rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 6,217,578 to Crozet et al. (hereafter “Crozet”) in view of U.S. Patent No. 5,545,167 to Lin (hereafter “Lin”); claims 8, 9 and 12 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Crozet in view of Lin and in further view of U.S. Patent Publication No. 2003/0114853 to Burgess et al. (hereafter “Burgess”); claims 13-15, 24-28, 37 and 38 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Crozet in view of Lin and in further view of U.S. Patent No. 5,976,135 to Sherman et al. (hereafter “Sherman”); claims 35, 36, 54, 55 and 57 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Crozet in view of Lin and in further view of U.S. Patent No. 6,554,832 to Shluzas (hereafter “Shluzas”); and claim 62 has been rejected under 35 U.S.C. §103(a) as being unpatentable over Crozet in view of Lin and in further view of U.S. Patent No. 7,137,986 to Troxell et al. (hereafter “Troxell”).

Additionally, claims 39-42 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Crozet in view of Lin and in further view of U.S. Patent No. 5,501,684 to Schlapfer et al.; and claims 44-46, 49, 51 and 52 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Crozet in view of Schlapfer.

The seminal case directed to application of 35 U.S.C. §103 is Graham v. John Deere, 383 U.S. 1, 148 U.S.P.Q. 459 (1966). From this case, four familiar factual inquiries have resulted. The first three, determining the scope and content of the prior art, ascertaining differences between the prior art and the claims at issue and resolving the level of ordinary skill in the pertinent art, are directed to the evaluation of prior art relative to the claims of the pending application. The fourth factual inquiry is directed to evaluating evidence of secondary considerations. See, Manual of Patent Examining Procedure (MPEP) §2141. While performing this analysis, the cited references must be considered in their entirety, i.e., as a whole, including portions that would lead away from the claimed invention. See, MPEP §2141.02 (citing W.L. Gore & Associates, Inc. v. Garlock, Inc., 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983)). From these inquiries, the initial burden is on the Examiner to establish a *prima facie* case of obviousness.

Additionally, the Supreme Court in the recent decision of KSR International Co. v. Teleflex Inc., 550 U.S. 398, 82 USPQ2d 1385, 127 S.Ct 1727, 167 L.Ed.2d 705 (U.S. 2007), citing In Re Kahn, 441 F.3d 977, 988 (CA Fed. 2006), stated:

[R]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.

KSR, 82 USPQ2d at 1396. For at least the following reasons, it is respectfully submitted that a *prima facie* case of obviousness has not been established in this case.

Claim Amendments

Claim 3 has been amended to recite further features associated with the claimed invention. Additionally, claim 33 has been cancelled and claim 64 has been added.

Arguments in Support of Patentability

Independent Claim 1 and Dependent Claims 2-31, 34-42 and 59-63

As indicated above, independent claim 1 stands rejected as being unpatentable over Crozet in view of Lin. Independent claim 1 recites, in combination with other elements and features:

an interconnection element including a first body and a stud, said first body having a first aperture formed therein and said stud extending from the body, said first aperture including an upper portion formed having a lobed shape; a first rod connector including a first shaft terminating in a first rod engaging portion and a lobe extending laterally from an end of said first shaft and displaced axially along said first shaft from the first rod engaging portion, said first shaft and said lobe slideably received within the first aperture such that said lobe passes through said first aperture and upon rotation of said first rod connector said lobe prevents said first rod connector from being removed from said first aperture.

For at least the reasons that follow, it is respectfully submitted that independent claim 1 is patentable over the cited references.

The outstanding Office Action asserts that Crozet discloses all the features of independent claim 1 except for a first shaft and lobe being slideably received within a first aperture such that the lobe passes through the first aperture, and upon rotation of the first rod

connector the lobe prevents the first rod connector from being removed from the first aperture. (See page 6). However, in an attempt to overcome this deficiency, the Office Action cites Lin and asserts that it would have been obvious “to have substituted the fastening mechanism of Crozet et al. with a fastening mechanism as taught by Lin in order to achieve the predictable result of preventing a shaft from being removed from an aperture”. (See page 7, lines 10-12).

As the Applicant previously submitted, the rationale required by KSR for modifying Crozet in the manner suggested is missing. Notably, the rationale provided by the Office Action in support of the suggested modification of Crozet is to achieve the predictable result of preventing a shaft from being removed from an aperture. As previously indicated by the Applicant, and as also acknowledged by the previous Office Action, Crozet clearly discloses an arrangement where a shaft is prevented from being removed from an aperture. As a corollary, the Crozet arrangement already achieves the function upon which the Office Action bases its rationale in support of the suggested modification.

KSR instructs that an Examiner must “identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does.” KSR, 82 USPQ2d at 1396. Additionally, the Examiner must make “explicit” this rationale of “the apparent reason to combine the known elements in the fashion claimed” (emphasis added), including a detailed explanation of “the effects of demands known to the design community or present in the marketplace” and “the background knowledge possessed by a person having ordinary skill in the art.” Id. Despite these clear requirements of KSR, the Office Action has not provided any rationale or reason that would have prompted one skilled in the art to modify Crozet in the manner suggested in the Office Action. Notably, since Crozet already achieves the function upon which the Office Action bases its rationale in support of the suggested modification, this rationale is flawed and would not prompt those skilled in the art to undertake the suggested modification. More specifically, those skilled in the art would not be prompted to, nor would they, modify Crozet in order to achieve a result that it already provides. Indeed, doing so would involve increased development time and additional expense without providing any different result. Similarly, the rationale set forth in the Office Action in support of the suggested modification of Crozet is flawed, and its use to support the suggested modification of Crozet is in error.

Thus, in view of the foregoing, it is respectfully submitted that the rationale required by KSR to support the suggested modification of Crozet has not been provided. The outstanding Office Action has also failed to address these deficiencies in support of the obviousness rejection of independent claim 1. Notably, the “Response to Arguments” section of the outstanding Office Action does not provide any alternative rationale in support of the suggested modification of Crozet, nor does it provide any indication that the asserted rationale comports with the requirements of KSR. Accordingly, a *prima facie* case of obviousness with regard to independent claim 1 has not been established for at least these reasons.

Furthermore, as the Applicant also previously submitted, Crozet also teaches away from the modification suggested in the Office Action. Notably, the combination of the flange 62 and the lock nut 52 provides a provisional locking of the cross connector 10, where the first and second rod gripping elements 18, 20 are movable relative to one another to facilitate adjustments to the cross connector 10 as it is positioned relative to spinal rods 12 and 14. In contrast to this arrangement, the connection assembly of Lin fails to provide any provisional locking where the elements remain movable relative to one another. Likewise, those skilled in the art would be lead away from and would not employ the fastening mechanism of Lin in the Crozet device since doing such would eliminate the ability to adjust the positioning of the components of the cross connector 10 when the components are provisionally assembled together.

In response, the outstanding Office Action asserts that “[t]he fastening mechanism of Lin limits some of the adjustability of the shaft [sic] it still performs the same function as Crozet to ultimately fasten the first shaft in the first aperture and is capable of adjustment while the shaft of Lin is located in the aperture through the use of various washers and connectors (fig 3, 200, 400, 500, 600) disclosed in figure 3”. The Applicant respectfully traverses this assertion. Notably, the provisional locking of cross connector 10 would be eliminated if it were modified in the manner suggested by the Office Action, even if the washers and connectors illustrated in Figure 3 of Lin were employed. More particularly, even when the retaining bolt 200 is used with the washers 500, 600, 700 in combination with the fastening nut 400, the retaining bolt 200 is not provisionally locked by any of these components while still retaining adjustability relative to the same. Rather, once the retaining bolt 200 is inserted through the washers 500, 600, 700, it may freely fall back through the washers 500, 600, 700 unless it is rotated ninety degrees to engage

with the fastening nut 400. However, once the retaining bolt 200 is rotated to engage with the fastening nut 400, the connection assembly of Lin becomes locked and the retaining bolt 200 is no longer axially adjustable relative to the connection element 300. In contrast, the cross connector 10 of Crozet allows positioning of the arm 28 relative to the pivot element 44 while also preventing disengagement of the arm 28 from the pivot element 44. Thus, in view of the foregoing, the suggested modification of Crozet would clearly eliminate positioning of the arm 28 relative to the pivot element 44 while also preventing disengagement of the arm 28 from the pivot element 44. As a corollary, those skilled in the art would be lead away from and would not employ the fastening mechanism of Lin in the Crozet device. Moreover, given the foregoing analysis, it should be clear that the fastening mechanism of Lin does not perform the same function as Crozet, as asserted in the Office Action.

For at least the reasons set forth above, the Applicant submits that independent claim 1 is patentable over the cited references. Accordingly, the Applicant respectfully requests withdrawal of the rejection of independent claim 1 and allowance of the same. Claims 2-31, 33-42 and 59-63 depend either directly or indirectly from independent claim 1 and are submitted to be patentable for at least the reasons supporting the patentability of independent base claim 1, although further reasons support the patentability of these claims.

For example, claim 3 has been amended and now recites “wherein said upper portion of the first aperture is positioned adjacent said stud and opposite of a lower portion, said lower portion including a semi-circular configuration and said upper portion including a non-circular configuration”. Support for the amendment to claim 3 is found, for example, in Figures 1, 2 and 5 of the subject application. It is respectfully submitted that none of the cited references disclose the arrangement recited in claim 3. For example, as illustrated in Figures 4A and 4B of Crozet, the lower portion of the bore of the pivot element 44 includes a curved surface positioned between a pair of linear surfaces. Accordingly, it is believed that the subject matter of claim 3, as a whole, has not been accounted for by the cited references, and allowance of the same is respectfully requested.

As another example, claim 8 recites “wherein the first shaft is curved so as to be non-linear,”, and claim 9 depends from claim 8 and further recites that the second shaft is curved. In the Applicant’s previous response, it was noted that the rationale required by KSR was missing,

and that those skilled in the art would not have modified Crozet to include curved shafts as asserted in the Office Action. In response, the outstanding Office Action asserts that since Burgess teaches straight shafts and curved shafts as alternatives, it allows for the shafts of Crozet to be either straight or curved and to perform the function of connecting two rods. (See Office Action, page 15). Despite this assertion, the Applicant notes that the Office Action has still failed to provide any reason that would have prompted those skilled in the art to actually modify Crozet in the suggested manner, as required by KSR. Indeed, as discussed above with respect to independent claim 1, those skilled in the art would not be prompted to modify a device in order to perform a function that is already performed by the device. Claim 12, which recites “wherein the first shaft and the second shaft are curved,” is further patentable over the cited references for at least these reasons as well.

Claim 24 recites that the assembly of independent claim 1 further comprises “a washer carried by the stud and positioned in the second body of the second rod connecting member, wherein engagement of the fastener to the stud urges the washer to contact the first shaft of the first rod connecting member and clamp the first rod connecting member in a first orientation relative to the second rod connecting member.” As previously submitted, it does not appear that any of the references disclose a washer positioned in the body of a second rod connecting member. For example, with respect to Sherman, the washer 55 is not positioned within a body of a second rod connecting member. In response, the outstanding Office Action asserts that the splines of the washer mate with the splines of the body such that part of the washer is within the body of the connecting member. (See Office Action, page 15). This assertion is respectfully traversed. Notably, even assuming arguendo that a part of the washer is positioned within a body (as asserted in the Office Action), the Applicant notes that Crozet fails to disclose any structure to facilitate this type of positioning, nor has the Office Action provided any evidence of the same or otherwise accounted for this particular arrangement of features. Accordingly, claim 24 is believed to be patentable over the cited references for these additional reasons.

Furthermore, claim 60 recites “wherein said stud has a longitudinal axis, and said first shaft has a longitudinal axis, and said stud longitudinal axis is oblique to said first shaft longitudinal axis.” The Office Action indicates that the Crozet/Lin combination discloses these features. However, it is respectfully submitted that Crozet and Lin both fail to disclose this

particular arrangement of features. More particularly, as previously submitted by the Applicant, in connector 10 of Crozet, the axis 42 of pivot element 44 extends perpendicularly, and not obliquely, to the axis 64 of the arm 28. In response, the outstanding Office Action asserts that when the first shaft is not locked the orientation of the shaft can change in the aperture, in which case the angle will be oblique. (See Office Action, page 15). However, even when the arm 28 is not locked in the pivot element 44, its movement is limited to rotation about its axis 64 and axial sliding relative to the pivot element 44. Thus, in contrast to the assertion set forth in the Office Action, at no point can the arm 28 be positioned obliquely to the axis 42 of the pivot element 44. Accordingly, it is respectfully submitted that claim 60 is also patentable over the cited references.

As another example, claim 62 recites:

wherein said interconnection element includes a pair of flanges extending outwardly diametrically opposite each other circumferentially about an external surface of said first body, and said second body includes a pair of internal flanges in said second aperture, wherein said flanges of said interconnection element allow said flanges of said second body to pass through gaps between said flanges of said interconnection element during assembly and upon rotation of said second body said flanges of said interconnection element engage said flanges of said second body.

The Office Action acknowledges that the Crozet/Lin combination fails to disclose these features. However, Troxell is advanced for disclosing an interconnection element that comprises flanges that extend into an aperture in order to lock the components together. (See page 12). Even assuming arguendo that Troxell could somehow be construed to disclose these features, the Applicant notes that Troxell still fails to disclose a second body that includes a pair of internal flanges in an aperture, as recited in claim 62. Accordingly, the subject matter of claim 62 has not been accounted for in the Office Action, and claim 62 is further patentable over the cited references.

Independent Claim 43

Independent claim 43 stands rejected as being unpatentable over Crozet in view of Lin. Independent claim 43 is directed to a method that includes, among other features, “interconnecting the first spinal rod to the second spinal rod using the assembly of claim 1”. It is

respectfully submitted that independent claim 43 is patentable over the cited references for at least the reasons set forth above in support of the patentability of independent claim 1.

Accordingly, withdrawal of this rejection and allowance of independent claim 43 are respectfully requested.

Independent Claim 44 and Dependent Claims 45, 46, 49 and 51

As indicated above, independent claim 44 stands rejected as being unpatentable over Crozet in view of Schlapfer. Independent claim 44 recites, in combination with other elements and features:

an insert positioned over said stud having a lower surface configured to engage the first shaft of the first rod connecting member extending through the third aperture and an upper portion positioned in said first aperture of said second body; and a fastener extending through the first aperture of the second body and into an internal recess of the insert to fixedly engage the stud thereby securing the orientation of the first rod connector relative to the second rod connector.

For at least the reasons that follow, it is respectfully submitted that independent claim 44 is patentable over the cited references.

The Office Action asserts that Crozet discloses all the features of independent claim 44 “except for an insert disposed in the second aperture that encircles the stud and a fastener that extends through the first aperture and into an internal recess in the insert to fix the orientation”. (See page 13). However, the Office Action asserts that Schlapfer “discloses an insert that is positioned in an aperture of a connection device and surrounds a stud and a fastener (fig 10, 11g) that extends through the first aperture and into an internal recess in the insert to allow for adjustments in all directions”. (See page 14). Moreover, the Office Action goes on to assert that it would have been obvious to modify Crozet “with an insert disposed in the second aperture that encircles the stud in view of Schlapfer et al. in order to allow for adjustment in all directions”. (See page 14). As will be discussed in greater detail below, a *prima facie* case of obviousness has not been established with regard to independent claim 44 in view of the Crozet/Schlapfer combination.

As an initial matter, the Applicant notes that the Office Action has not provided any rationale for modifying Crozet to include a fastener that has the features and that is arranged as

specified in independent claim 44. Notably, the Office Action only asserts that it would have been obvious to include an insert to allow for adjustments in all directions. As indicated above, KSR instructs that an Examiner must “identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does”. KSR, 82 USPQ2d at 1396. Additionally, the Examiner must make “explicit” this rationale of “the apparent reason to combine the known elements in the fashion claimed” (emphasis added), including a detailed explanation of “the effects of demands known to the design community or present in the marketplace” and “the background knowledge possessed by a person having ordinary skill in the art.” Id. Notwithstanding these requirements of KSR, the Office Action has not provided any reason that would have prompted those skilled in the art to modify Crozet to include a fastener that has the features arranged as in independent claim 44. Accordingly, a *prima facie* case of obviousness of independent claim 44 has not been established for at least this reason.

In addition to the foregoing, Schlapfer does not disclose “a fastener extending through the first aperture of the second body and into an internal recess of the insert to fixedly engage the stud thereby securing the orientation of the first rod connector relative to the second rod connector”. As indicated above, the Office Action asserts that hollow pin 11g illustrated in Figure 10 of Schlapfer corresponds to the fastener of independent claim 44. As illustrated in Figure 10 of Schlapfer, the hollow pin 11g is inserted over fixation element 1 into clamping piece 2 which is seated in connecting element 3. (See column 4, lines 25-30 and column 6, lines 54-61). A fastening element 6 is then threaded onto the fixation element 1 against the hollow pin 11g in order to apply a radially expanding force to the clamping piece 2 to lock the clamping piece 2 relative to the connecting element 3. (See e.g., column 6, lines 54-61).

In contrast to the fastener of independent claim 44, the hollow pin 11g does not extend through a first aperture of a second body and into an internal recess of an insert. Rather, the hollow pin 11g only extends into the clamping piece 2. Additionally, the hollow pin 11g does not fixedly engage the fixation element 1 to secure the orientation of a first rod connector relative to a second rod connector. Rather, as discussed above, it is the threading of the fastening element 6 onto fixation element 1 that locks the clamping piece 2 relative to the connecting element 3. However, in contrast to the fastener of independent claim 44, the fastening element 6

does not extend through a first aperture and into an internal recess of an insert. Thus, for at least these reasons, Schlapfer does not disclose a fastener that has the features arranged as recited in independent claim 44. Accordingly, the Crozet/Schlapfer combination fails to account for the subject matter of independent claim 44 as a whole. Likewise, a *prima facie* case of obviousness has not been established with respect to independent claim 44 for this reason as well.

For at least the reasons set forth above, the Applicant submits that independent claim 44 is patentable over the cited references. Accordingly, the Applicant respectfully requests withdrawal of the rejection of independent claim 44 and allowance of the same.

Claims 45, 46, 49 and 51 depend either directly or indirectly from independent claim 44 and are submitted to be patentable for at least the reasons supporting the patentability of independent base claim 44.

Independent Claim 52

Independent claim 52 stands rejected as being unpatentable over Crozet in view of Schlapfer. Independent claim 52 is directed to a method that recites the step of “interconnecting the first spinal rod to the second spinal rod using the assembly of claim 44”. It is respectfully submitted that independent claim 52 is patentable over the cited references for at least the reasons supporting the patentability of independent claim 44. Accordingly, withdrawal of this rejection and allowance of independent claim 52 are respectfully requested.

Independent Claim 53 and Dependent Claims 54, 55, 57 and 64

As indicated above, independent claim 53 stands rejected as being unpatentable over Crozet in view of Lin. Independent claim 53 recites, in combination with other features and elements:

said projection being able to move through said aperture when said shaft is in a first orientation with respect to said aperture, and being unable to move through said aperture when said shaft is in a second orientation with respect to said aperture different from said first orientation and a single fastener to secure the first and second spinal rod connectors to each other at a user defined orientation relative to each other.

For at least the reasons that follow, it is respectfully submitted that independent claim 53 is patentable over the cited references.

The Office Action asserts that Crozet discloses all the features of independent claim 53 except for “a projection being able to move through said aperture when said shaft is in a first orientation with respect to said aperture, and being unable to move through said aperture when said shaft is in a second orientation with respect to said aperture different from said first orientation”. (See Office Action, paragraph spanning pages 6-7). However, as indicated above with respect to independent claim 1, the Office Action attempts to overcome this deficiency by citing Lin and asserting that it would have been obvious “. . . to have substituted the fastening mechanism of Crozet et al. with a fastening mechanism as taught by Lin in order to achieve the predictable result of preventing a shaft from being removed from an aperture”. (See Office Action, page 7, lines 10-12).

As discussed above with regard to independent claim 1, the rationale required by KSR for modifying Crozet to include the fastening mechanism of Lin is missing. Moreover, as also discussed above with regard to independent claim 1, those skilled in the art would be lead away from modifying Crozet in the manner suggested by the Office Action since doing so would eliminate the ability to adjust the positioning of the components of the cross connector 10 when the components are provisionally assembled together. Additionally, even assuming *arguendo* that Crozet could somehow be modified to include the fastening mechanism of Lin, the Applicant notes that the resulting device would not include a single fastener to secure the first and second spinal rod connectors to each other, as recited in independent claim 53. Notably, the fastening mechanism of Lin includes a pair of fastener components (i.e., washer 500 and fastening nut 400). As a corollary, even if Crozet were somehow modified as asserted in the Office Action, the subject matter of independent claim 53, as a whole, would still not be accounted for.

For at least the reasons set forth above, the Applicant submits that independent claim 53 is patentable over the cited references. Accordingly, the Applicant respectfully requests withdrawal of the rejection of independent claim 53 and allowance of the same. Claims 54, 55, 57 and 64 depend either directly or indirectly from independent claim 53 and are submitted to be patentable for at least the reasons supporting the patentability of independent base claim 53, although further reasons support the patentability of these claims.

For example, claim 64 has been added and recites “wherein said projection extends along said first shaft from said end toward said proximal portion”. Support for claim 64 is found, for example, in Figures 1, 2 and 7 of the subject application. The Applicant respectfully submits that none of the cited references discloses the arrangement recited in claim 64. For example, in both Crozet and Lin, the flange 62 and the rectangular head 220 extend across the end of a shaft, and not along the shaft from the end toward a proximal portion. Accordingly, entry and allowance of claim 64 are respectfully requested.

Independent Claim 58

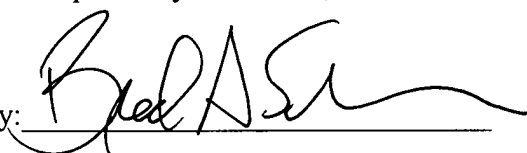
Independent claim 58 also stands rejected as being unpatentable over Crozet in view of Lin. Independent claim 58 is directed to a method that recites the step of “interconnecting the first spinal rod to the second spinal rod using the apparatus of claim 53”. It is respectfully submitted that independent claim 58 is patentable over the cited references for at least the reasons supporting patentability of independent claim 53. Accordingly, withdrawal of this rejection and allowance of claim 58 are respectfully requested.

CONCLUSION

In view of the foregoing amendments and remarks, it is respectfully submitted that the subject application is now in condition for allowance with pending claims 1-31, 34-46, 49, 51-55 and 57-64.

Reconsideration of the subject application is respectfully requested. Timely action towards a Notice of Allowability is hereby solicited. The Examiner is encouraged to contact the undersigned by telephone to resolve any outstanding matters concerning the subject application.

Respectfully submitted,

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